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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 52i

[Docket Number NIH-2007-0931]

RIN 0925-AA61

National Institute on Minority Health and Health Disparities Research Endowments

AGENCY: National Institutes of Health, Department of Health and Human Services

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to issue regulations governing National Institute on Minority Health and Health Disparities (NIMHD) endowment grants awarded to section 736 and section 464z-4 Centers of Excellence to facilitate minority health disparities research and other health disparities research.

DATES: Comments must be received on or before [*Federal Register*: insert the date 60 days following the date of publication] in order to ensure that the NIH will be able to consider the comments when preparing the final rule.

ADDRESSES: Individuals and organizations interested in submitting comments, identified by RIN 0925-AA47 and Docket No. NIH-2007-0931, may do so by any of the following methods:

#### *Electronic Submissions*

You may submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timely processing of comments, the NIH is no longer accepting comments submitted to the agency by e-mail. The NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal:  
<http://www.regulations.gov>.

#### *Written Submissions*

You may submit written comments in the following ways:

- Fax: 301-402-0169 (not a toll-free number).
- Mail: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852-7669.

*Instructions:* All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to the eRulemaking.gov Portal and insert the docket number provided in brackets in the heading on page one of this document into the “Search” box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address above or telephone 301-496-4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 464z-3 (42 USC 285t) of the Public Health Service (PHS) Act authorizes the Director of the NIMHD to carry out a program to facilitate minority health disparities research and other health disparities research by providing research endowments to eligible centers of excellence under sections 736 and 464z-4 of the PHS Act. The program is called the NIMHD Research Endowment Program (Endowment Program). The objective of the Endowment Program is to build research and training capacity and infrastructure at eligible section 736 health professions schools (42 U.S.C. 293) and section 464z-4 biomedical and behavioral research institutions (42 U.S.C. 285t-1) to facilitate minority health and other health disparities research to close the disparity gap in the burden of illness and death experienced by racial and ethnic minority Americans and other health disparity populations. Endowment Program activities may include strengthening the research infrastructure through the

renovation of facilities, purchasing of state-of-the-art instruments and equipment, and enhancing information technology; enhancing the academic environment by recruiting a diverse faculty and creating relevant courses in such topics as research methodology and health disparities as additions to the existing curriculum; enhancing recruitment of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences; or other relevant activities.

Section 464z-4 of the PHS Act authorizes the NIMHD Director to make awards to designated biomedical and behavioral research institutions, alone or as a participant in a consortium, that meet certain criteria for the purpose of assisting the institutions in supporting programs of excellence in training for members of health disparity populations or other health disparity populations. This program is called the NIMHD Center of Excellence for Research and Training. Section 464z-4(f) of the PHS Act permits the NIMHD Director to expend a portion of such an award for research endowment.

To be eligible to apply for the Endowment Program, Centers of Excellence (funded under section 736 or section 464z-4 of the PHS Act) must have an institutional endowment that is equal to or less than 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research and training of health professionals. Endowment Program applications filed by institutions meeting eligibility requirements undergo peer review by outside experts to evaluate the scientific and technical merit of the proposed activities and the adequacy of the endowment fund management plan.

Reviewers use the criteria of significance, investigators, innovation, approach, and environment to determine the overall impact of the application. After receiving an Endowment Program award, a grantee must provide documentation to the NIMHD over a 20-year period regarding endowment fund activity, including investments, income, and expenditures for activities consistent with its strategic plan.

With this notice of proposed rulemaking (NPRM), the NIH is announcing its proposed regulations governing endowments and inviting the public to comment on this proposal.

This NPRM specifies the endowment research grants or endowment portion of an award to which the proposed regulations apply (section 52i.1), the definitions (section 52i.2), who is eligible (section 52i.3) and how to apply for a grant under the program (section 52i.5), and under what conditions an eligible institution that is a recipient may transfer to a foundation a research endowment grant (section 52i.4). Additionally, the NPRM specifies how endowment grant applications will be evaluated (section 52i.6), what is the nature of the grants (52i.7), how much endowment fund income a grantee may withdraw and for what purpose (sections 52i.9 and 52i.10), what a grantee must record and report (section 52i.11), and when and for what purposes a grantee may spend the endowment fund corpus (section 52i.8). This NPRM also specifies what happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations (section 52i.12), what other HHS policies and regulations apply (section 52i.13), and what additional conditions the NIMHD Director may impose when, in his judgment, the conditions are necessary (section 52i.14).

The following is provided as public information.

#### Regulatory Impact Analyses (RIA)

We have examined the impacts of the this rule as required by Executive Order 12866, Regulatory Planning and Review (September 30, 1993); Executive Order 13563, Improving Regulation and Review (January 18, 2011); the Regulatory Flexibility Act (5 U.S.C. 601–612); the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and Executive Order 13132, Federalism (August 4, 1999).

#### Executive Orders 12866 and 13563

Executive Order 12866, Regulatory Planning and Review, directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A RIA must be prepared for major rules with economically significant effects (\$100 million or more in one year). Based on our analysis, we believe that the proposed rulemaking does not constitute an economically significant regulatory action.

Additionally, if a regulatory action is deemed to fall within the scope of the definition of the term “significant regulatory action” contained in section 3(f) of Executive Order 12866, pre-publication review by the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) is required. This proposed rule was

reviewed under the criteria of Executive Order 12866 and was not deemed a “significant regulatory action.”

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

#### Benefits

The proposed regulations will add transparency for potential applicants regarding who is eligible and how to apply for a grant under the program, how grant applications will be evaluated, and under what conditions an eligible institution that is a recipient may transfer to a foundation a research endowment grant. Additionally, the NPRM specifies the nature of the grants, how much endowment fund income a grantee may withdraw and for what purpose, what a grantee must record and report, and when and for what purposes a grantee may spend the endowment fund corpus.

This NPRM also enhances compliance and effective fiduciary responsibilities for the federal government. It specifies what happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations, what other HHS policies and regulations apply, and additional conditions the NIMHD Director may

impose when, in his judgment, the conditions are necessary. The Director may, with respect to any grant award, impose additional conditions prior to, or at the time of, any award when in the Director's judgment the conditions are necessary to ensure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

### Costs

Based on the provisions of the PHS Act, approximately twelve Institutions of Higher Education (IHEs) are eligible for the NIMHD Research Endowment Program. Costs for participation can be subdivided into those associated with the application process and those required for the necessary recordkeeping. The application process includes a competitive submission, as well as noncompetitive progress report for those institutions awarded funds under the NIMHD Research Endowment Program for subsequent years within the project period. Based on estimates provided in the PHS 424 instructions, an average application should require approximately 22 hours to complete and 15 hours for a subsequent progress report, according to the PHS 2590 instructions. The contribution of various professional disciplines such as biomedical researchers, contract/grants specialists, and technical staff to the reporting and recordkeeping requirements varies. Cost estimates are based on a blended analysis of institutional salary structure and prevailing market conditions for certain categories of personnel. In addition, fiscal year 2012 NIH salary limitations were included in the derivation of cost estimates, where applicable.



	Annual number of respondents <sup>1</sup>	Annual frequency	Estimated cost per response <sup>2</sup>	Estimated annual costs <sup>3</sup>
Reporting:				
§52i.3(b)(2).....	4	1	\$134.60 <sup>4</sup>	\$538.40
§52i.4(a).....	4	1	\$33.65 <sup>5</sup>	\$134.60
§52i.4(c).....	4	1	\$33.65 <sup>6</sup>	\$134.60
§52i.5(a).....	4	1	\$3,602.00 <sup>7</sup>	\$14,408.00
§52i.9(b).....	4	1	\$345.56 <sup>8</sup>	\$1,382.24
§52i.11(b).....	12	1	\$1,775.00 <sup>9</sup>	\$21,300.00
§52i.11(d).....	12	1	\$200.00 <sup>10</sup>	\$2,400.00
Subtotal.....	.....	.....		\$40,297.84
Recordkeeping:				
§52i.10.....	12	1	\$400.00 <sup>11</sup>	\$4,800.00
§52i.11(a)(1).....	12	1	\$67.30 <sup>12</sup>	\$807.60
§52i.11(a)(2).....	12	1	\$67.30 <sup>13</sup>	\$807.60
§52i.11(a)(3).....	12	1	\$67.30 <sup>14</sup>	\$807.60
§52i.11(a)(4).....	12	1	\$67.30 <sup>15</sup>	\$807.60
§52i.11(b).....	12	1	\$269.20 <sup>16</sup>	\$3,230.40
Subtotal.....	.....	.....		\$11,260.80
Total.....				\$51,558.64

<sup>1</sup> There is currently a total of twelve institutions eligible for the NIMHD Research Endowment Program. Historically, requests for applications are solicited every three years.

<sup>2</sup> Average burden hours x average cost per hour.

<sup>3</sup> Annual number of respondents x cost per response.

<sup>4,5,6</sup> Based on contracts/grants staff at \$33.65/hour.

<sup>7</sup> Based on the contributions of the principal investigator at \$86.39/hour, participating faculty at \$72.12/hour, contracts/grants staff at \$33.65/hour, financial investment advisor at \$200/hour, and administrative support at \$16.83/hour.

<sup>8</sup> Based on principal investigator at \$86.39/hour.

<sup>9</sup> Based on the contributions of the principal investigator at \$86.39/hour, participating faculty at \$72.12/hour, contracts/grants staff at \$33.65/hour, financial investment advisor at \$200/hour, and administrative support at \$16.83/hour.

<sup>10</sup> Based on financial analyst/auditor at \$100/hour.

<sup>11</sup> Based on financial investment advisor at \$200/hour.

<sup>12,13,14,15</sup> Based on contracts/grants staff at \$33.65/hour.

<sup>16</sup> Based on contracts/grants staff at \$33.65/hour.

## Alternatives

The unique and complex nature of the NIMHD Research Endowment Program with regard to the management of endowment funds, restrictive nature of expenditures, and strict reporting provides a challenge to the necessary federal oversight. The proposed draft rule provides the guidelines for the creation of an operation structure of the institutional program. The implementation of the draft rule would provide clarity to eligible and participating institutions with regard to expectations as a grantee under the program, as well as enhance the ability of the federal government to ensure the grantees are in compliance with all the applicable provisions of the statute.

## The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purposes of this analysis, small entities include small business concerns as defined by the Small Business Administration, usually businesses with fewer than 500 employees. Eligibility requirements of the Research Endowment program, as codified in Public Law 111-148, limits the universe of potential applicants to approximately twelve IHEs. Utilizing sources of information such as local business bureaus, workforce statistics, and institution websites, a reasonable determination was made as to the approximate number of employees at eligible institutions. The range estimates are from 175-550 for the smallest institution to 3,976 for the largest. Consequently, less than 10 percent of these eligible IHEs have fewer than 500 employees. Accordingly, the

Secretary certifies that any final rule resulting from this proposed rule will not have a significant impact on a significant number of small entities.

#### Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation [with base year of 1995]) in any 1 year.” The current inflation-adjusted statutory threshold is approximately \$139 million based on the Bureau of Labor Statistics inflation calculator. The Secretary certifies that this rule does not mandate any spending by state, local or tribal government in the aggregate or by the private sector. Participation in the NIMHD Research Endowment Program is voluntary and not mandated.

#### Executive Order 13132

Executive Order 13132, Federalism, requires federal agencies to consult with state and local government officials in the development of regulatory policies with federalism implications. The Secretary reviewed the proposed rule as required under the Executive Order and determined that it does not have federalism implications. The Secretary certifies that the proposed rule will not have an effect on the states or on the distribution of power and responsibilities among the various levels of government.

## Paperwork Reduction Act

This proposed rule contains requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35). Sections 52i.3(b)(2), 52i.4(a), 52i.4(c), 52i.5(a), 52i.9, 52i.11(b), and 52i.11(d) contain reporting and information collection requirements that are subject to OMB approval under the Paperwork Reduction Act. Sections 52i.10, 52i.11(a)(1), 52i.11(a)(2), 52i.11(a)(3), 52i.11(a)(4), and 52i.11(b) contain recordkeeping requirements that are subject to OMB review under the Paperwork Reduction Act. The title, description, and respondent description of the information collection and recordkeeping requirements contained in this proposed rule have been submitted to OMB for review. Other organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements, including the burden estimates provided, should send their comments to: (1) Seleda Perryman, Project Clearance Officer, National Institutes of Health, Rockledge Center 1, 6705 Rockledge Drive, Room 3509, Bethesda, MD 29817, telephone 301-594-7949 (not a toll-free number); and (2) the Office of Information and Regulatory Affairs, OMB, [OIRA\\_submission@omb.eop](mailto:OIRA_submission@omb.eop) or by fax to 202-395-6974, and mark “Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services.” After we obtain OMB approval, we will publish the OMB control number in the *Federal Register*.

Title: National Institute on Minority Health and Health Disparities Research Endowments.

Description: The NIMHD Research Endowment Program builds research capacity and research infrastructure in order to facilitate minority health research and

research regarding other health disparity populations at eligible institutions under sections 736 and 464z-4 of the PHS Act.

Respondent Description: Institutions currently funded under Section 736 or Section 464z-4 of the Public Health Service Act (PHS Act).

**ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN  
NIMHD RESEARCH ENDOWMENT PROGRAM**

	Annual number of respondents	Annual frequency	Average burden hours	Annual burden hours per response <sup>17</sup>
<b>Reporting:</b>				
§52i.3(b)(2).....	4	1	4	16
§52i.4(a).....	4	1	1	4
§52i.4(c).....	4	1	1	4
§52i.5(a).....	4	1	22	88
§52i.9(b).....	4	1	4	16
§52i.11(b).....	12	1	15	180
§52i.11(d).....	12	1	2	24
Subtotal.....	.....	.....	49	332
<b>Recordkeeping:</b>				
§52i.10.....	12	1	2	24
§52i.11(a)(1).....	12	1	2	24
§52i.11(a)(2).....	12	1	2	24
§52i.11(a)(3).....	12	1	2	24
§52i.11(a)(4).....	12	1	2	24
§52i.11(b).....	12	1	8	96
Subtotal.....	.....	.....	18	216
Total.....	.....	.....	67	548

<sup>17</sup>Annual number of respondents x annual frequency x average burden hours.

Catalogue of Federal Domestic Assistance

The Catalogue of Federal Domestic Assistance-numbered program applicable to this rule

is: 93.307 - Minority Health and Health Disparities Research

List of Subjects in 42 CFR Part 52i

Grant programs—Health, medical research

For reasons described in the preamble, it is proposed to amend title 42 of the Code of Federal Regulations by adding part 52i to read as follows.

**PART 52i – NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH  
DISPARITIES RESEARCH ENDOWMENT PROGRAMS**

Sec.

52i.1 To what programs does this part apply?

52i.2 Definitions.

52i.3 Who is eligible to apply?

52i.4 Under what conditions may an eligible institution designate a foundation as the recipient of a research endowment grant?

52i.5 How to apply for a grant.

52i.6 Evaluation and disposition of research endowment grant applications.

52i.7 Grant awards.

52i.8 When and for what purposes may a grantee spend the endowment fund corpus?

52i.9 How much endowment fund income may a grantee spend and for what purposes?

52i.10 How shall a grantee calculate the amount of endowment fund income that it may withdraw and spend?

52i.11 What shall a grantee record and report?

52i.12 What happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations?

52i.13 Other HHS policies and regulations that apply.

52i.14 Additional conditions.

Authority: 42 U.S.C. 216, 285t-285t-1.

**§ 52i.1 To what programs does this part apply?**

This part applies to grants awarded under section 464z-3(h) of the Public Health Service Act (the Act), which authorizes the Director of the National Institute on Minority Health and Health Disparities (NIMHD) to carry out a program of research endowment grants to eligible institutions to facilitate minority health and health disparities research (the NIMHD Research Endowment Program), and, with the exception of §§ 52i.5 and 52i.6, applies to that portion of an award made under section 464z-4(f) of the Act authorized by the NIMHD Director for research endowment.

**§ 52i.2 Definitions.**

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

Center of Excellence means, for purposes of grants authorized by section 464z-3(h) of the Act, an institution designated as a Center of Excellence and receiving a grant under section 736 (42 U.S.C. 293) or section 464z-4 (42 U.S.C 285t-1) of the Act.

Director means the Director, NIMHD, of the National Institutes of Health.



Endowment fund means a fund that is established by state law, by an institution, or by a foundation associated with an institution that is exempt from taxation and is maintained for the purpose of generating income for the support of minority and health disparities research or research training if the funds are from a grant made under section 464z-4 of the Act. The principal or corpus of the fund may not be spent except as noted in § 52i.8(b).

Endowment fund corpus means an amount equal to the total grant funds awarded under this part or equal to the amount designated as endowment under section 464z-4 of the Act.

Endowment fund income means the income generated from investing the corpus, i.e., the amount of which exceeds the endowment fund corpus.

Health disparity population means a population that, as determined by the Director of the NIMHD after consultation with the Director of the Agency for Healthcare Research and Quality, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

Health disparities research means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such

populations) that relates to health disparities, including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

Health disparity students means students of minority health disparity populations or other health disparities populations.

Institutional endowment (IE) means the corporate or system-wide endowment fund that is the sum total of the endowment assets of all campuses and their components. This includes, but is not limited to, endowments managed by an institution's foundations/associations as well as state university systems.

Institution system-wide means all campuses and components.

Minority health conditions means, with respect to individuals who are members of minority groups, all diseases, disorders, and conditions (including with respect to mental health and substance abuse):

- (1) Unique to, more serious, or more prevalent in such individuals;
- (2) For which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or
- (3) With respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

Minority health disparities research means basic, clinical, and behavioral research on minority health conditions, including research to prevent, diagnose, and treat such conditions.

Racial and ethnic minority or minority group means American Indians (including Alaska Natives, Eskimos, and Aleuts), Asian Americans, Native Hawaiians and other Pacific Islanders, Blacks, and Hispanics. Hispanic means individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

### **§ 52i.3 Who is eligible to apply?**

(a) To be eligible for a grant under section 464z-3(h) of the Act an applicant:

(1) Must be a Center of Excellence under section 736 (42 U.S.C. 293) or section 464z-4 (42 U.S.C. 285t-1) of the Act, and

(2) Must have an institutional endowment that is equal to or less than 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research and training of health professionals.

(b) To be eligible for a portion of a grant award to be expended as a research endowment under section 464z-4(f) of the Act, an applicant:

(1) Must be a designated biomedical and behavioral research institution under section 464z-4 of the Act, and

(2) Must submit those materials prescribed by the Director, NIMHD.

**§ 52i.4 Under what conditions may an eligible institution designate a foundation as the recipient of a research endowment grant?**

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by federal funds. Such legally independent entities are often referred to as “foundations,” although this term does not necessarily appear in the name of the organization. An institution awarded an endowment grant under section 464z-3(h) of the Act or using designated grant funds for endowment purposes under section 464z-4(f) of the Act may designate a foundation associated with the institution to receive the endowment funds only for investment purposes if:

(a) The institution assures in its application that the foundation is legally authorized to receive the endowment funds and to administer the endowment funds in accordance with the regulations set forth in this part;

(b) The foundation agrees to administer the endowment funds in accordance with the regulations in this part;

(c) The institution agrees to be liable for any violation by the foundation of any applicable regulation, including any violation resulting in monetary liability; and

(d) The grantee institution has control and is responsible for the administration of the grant accounts.

**§ 52i.5 How to apply for a grant.**

(a) Each institution interested in applying for a grant under section 464z-3(h) of the Act must submit an application at such time and in such form and manner as the Secretary may prescribe.

(b) An institution described in § 52i.3 that has received a grant under this part may apply for another grant under this part if:

(1)(i) The institution still meets the eligibility requirements in §52i.3; and

(ii) The institution is in the last year of funding provided by NIH under this part;

or

(2) The institution no longer has an active grant under this part from NIH.

**§ 52i.6 Evaluation and award of research endowment grant applications.**

All applications filed in accordance with this part and meeting the minimal eligibility requirements shall be evaluated and recommended by technical and scientific peer review. The review evaluation shall take into account, among other pertinent factors:

(a) The scientific and technical merit of the proposed project to facilitate minority health disparities research and other health disparities research;

(b) The likelihood of its producing meaningful results;

(c) The adequacy of the applicant's resources available for the project; and

(d) The adequacy of the applicant's plan for managing the endowment fund.

**§ 52i.7 Grant awards.**

(a) Within the limits of funds, and upon such review and recommendation as may be required by law, the Director shall award a grant to those applicants whose approved projects will in the Director's judgment best promote the purposes of this part.

(b) An institution described in § 52i.3 that receives a grant under this part or an institution described in section 464z-4(f) of the Act authorized to use grant funds for endowment purposes shall follow the spending rules under the law of the state in which the institution is located and the spending rules/policies adopted by the recipient

institution, provided that such spending rules are not inconsistent with applicable federal regulations/policies.

(c) Grants awarded under this part or grant funds designated for endowment purposes as described under section 464z-4(f) of the Act must be invested no later than 90 days after the start date of the grant.

(d) The institution, in investing the endowment fund established under this section, shall exercise the judgment and care, under the circumstances then prevailing, that a person of prudence, discretion, and intelligence would exercise in the management of such person's own affairs and avoid all appearances of conflict of interest in the management of this fund.

(e) The total amount of an endowment grant under this part or the designated amount of the grant under section 464z-4(f) of the Act must be maintained as corpus by the institution for 20 years from the date of award.

(f) In the case of situations in which investment conditions result in the corpus referred to in paragraph (e) of this section having a net market value less than the value of the funds at the time of their receipt, appropriate actions must be taken (e.g., careful review of the investment strategy) in order to preserve the value of the endowment corpus.

(g) An institution described in § 52i.3 receiving an endowment grant under section 464z-3(h) of the Act may not simultaneously receive endowment funds under section 464z-4(f) of the Act.

(h) Consistent with section 464z-4(f) of the Act, the Director, NIMHD, may designate for a research endowment some of the funds awarded to a Center of Excellence for research education and training.

**§ 52i.8 When and for what purposes may a grantee spend the endowment fund corpus?**

(a) A grantee may not withdraw or spend any part of the endowment fund corpus for a total of 20 years from the date of the original grant award.

(b) At the end of the 20-year period, during which the endowment corpus must be maintained, the grantee institution is encouraged to preserve the endowment fund corpus but may use the endowment fund corpus for any purpose that expands or develops the institution's minority health and/or health disparities research and/or training capacity.

**§ 52i.9 How much endowment fund income may a grantee spend and for what purposes?**

(a) Any endowment income realized in the initial year following the grant award under this part shall not be expended to support programmatic activities until after conclusion of the initial year of the grant.



(b) After the first year of the grant, a grantee awarded funds under this part may spend endowment income realized from funds it receives solely in accordance with the regulations of this part, the terms and conditions of the award, NIMHD policies and procedures, and the grantee's strategic plan that has been approved by the NIMHD and includes priorities for the use of the endowment fund income.

**§ 52i.10 How shall a grantee calculate the amount of endowment fund income that it may withdraw and spend?**

A grantee awarded funds under this part shall calculate the amount of endowment fund income that it may withdraw and spend at a particular time as follows:

(a) On each date that the grantee plans a withdrawal of endowment fund income, the grantee must determine the amount of the income by calculating the value of the fund that exceeds the endowment fund corpus.

(b) If the total value of the endowment fund exceeds the endowment fund corpus, the grantee may withdraw and spend the excess amount, i.e., the endowment fund income, in accordance with § 52i.9.

**§ 52i.11 What shall a grantee record and report?**

A grantee awarded funds under this part shall:

(a) Maintain appropriate records in compliance with this part and other requirements as referenced in terms of the award, including documentation of:

- (1) The type and amount of investments of the endowment fund;
- (2) The amount of endowment fund income and corpus;
- (3) The amount and purpose of expenditures of endowment fund income; and
- (4) The expenses and charges associated with the management of the endowment funds if such expenses and charges were paid from the grant funds.

(b) Retain records in accordance with 45 CFR 74.53. The endowment fund corpus, fund income, and fund expenditures must be reported over a 20-year period, and supporting records are to be retained for 3 years after the submission of the final report to the NIMHD;

(c) Permit authorized officials the authority to conduct a review, as set forth in 45 CFR 74.53(e) (which states that the Department of Health and Human Services (HHS) awarding agencies, the HHS Inspector General, the U.S. Comptroller General, and any of their duly authorized representatives “have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to

the awards, in order to make audits, examinations, excerpts, transcripts, or copies of such documents”); and

(d) Submit Financial Status Reports, as set forth in 45 CFR 74.52, as required by the NIMHD and in the form prescribed. A final Financial Status Report shall be required 20 years after the date of the original grant award.

**§52i.12 What happens if a grantee fails to administer the research endowment grant in accordance with applicable regulations?**

(a) The Director, after giving notice and an opportunity for a hearing, may authorize the termination of a grant awarded and/or recovery of funds under this part during the 20-year period if the grantee:

(1) Withdraws or spends any part of the endowment fund corpus in violation of this part;

(2) Spends any portion of the endowment fund income not permitted to be spent in this part;

(3) Fails to invest the endowment fund corpus in accordance with the investment standards set forth in this part;

(4) Fails to meet the requirements in § 52i.7; or

(5) Otherwise fails to comply with the terms and conditions of the award.

(b) Recovery of funds may include up to the amount of endowment awards plus any income earned.

**§ 52i.13 Other HHS policies and regulations that apply.**

Several other regulations and policies apply to grants under this part. These include, but are not limited to:

(a) 2 CFR part 376--HHS Nonprocurement debarment and suspension

(b) 42 CFR part 50, Subpart A--Responsibilities of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

(c) 42 CFR part 50, Subpart D--Public Health Service grant appeals procedures

(d) 45 CFR part 16--Procedures of the Departmental Grant Appeals Board

(e) 45 CFR part 46--Protection of human subjects

(f) 45 CFR part 74--Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial

organizations; and certain grants and agreements with states, local governments, and Indian tribal governments

(g) 45 CFR part 80--Nondiscrimination under programs receiving federal assistance through the Department of Health and Human Services--Effectuation of Title VI of the Civil Rights Act of 1964

(h) 45 CFR part 81--Practice and procedure for hearings under part 80 of this title

(i) 45 CFR part 82—Government-wide requirements for drug-free workplace (financial assistance)

(j) 45 CFR part 84--Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from federal financial assistance

(k) 45 CFR part 86--Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from federal financial assistance

(l) 45 CFR part 91--Nondiscrimination on the basis of age in HHS programs and activities receiving federal financial assistance

(m) 45 CFR part 92--Uniform administrative requirements for grants and cooperative agreements to state and local government

(n) 45 CFR part 93--New restrictions on lobbying

(o) 59 FR 34496 (July 5, 1994)--NIH Guidelines for Research Involving Recombinant DNA Molecules. [Note: this policy is subject to change, and interested persons should contact the Office of Biotechnology Activities, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892 (telephone 301-435-2152, not a toll-free number), to obtain references to the current version and any amendments. Information may be obtained also by contacting the Office of Biotechnology Activities via e-mail at [oba@od.nih.gov](mailto:oba@od.nih.gov) and via the OBA website at <http://www4.od.nih.gov/oba>.]

(p) 59 FR 14508 (March 28, 1994)--NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. [Note: this policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Suite 400, 6707 Democracy Boulevard, MSC 5484, Bethesda, MD 20892-5484 (telephone 301-402-1770, not a toll-free number), to obtain references to the current version and any amendments. Information may be obtained also by contacting the Office of Research on Women's Health website at <http://ORWH.od.nih.gov>.]

(q) NIH Grants Policy Statement (October 1, 2012). This version is located on the NIH website at [http://grants.nih.gov/grants/policy/nihgps\\_2012/index.htm](http://grants.nih.gov/grants/policy/nihgps_2012/index.htm). [Note: this policy is subject to change, and interested persons should contact the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH,

6701 Rockledge Drive, Suite 350, MSC 7974, Bethesda, MD 20892-7974 (telephone 301-435-0938 or toll-free 800-518-4726), to obtain references to the current version and any amendments. Information may be obtained also by contacting the OPERA Division of Grants Policy via e-mail at [GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov). Previous versions of the NIH Grants Policy Statement are archived at <http://grants.nih.gov/grants/policy/policy.htm>.]

(r) Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, NIH (Revised August 2002). [Note: this policy is subject to change, and interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge 1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, MD 20892-7982 (telephone 301-594-2382, not a toll-free number), to obtain references to the current version and any amendments. Information may be obtained also via the OLAW website at <http://grants.nih.gov/grants/olaw/olaw.htm>.]

**§ 52i.14 Additional conditions.**

The Director may, with respect to any grant award, impose additional conditions prior to, or at the time of, any award when in the Director's judgment the conditions are necessary to ensure the carrying out of the purposes of the award, the interests of the public health, or the conservation of grant funds.

Dated: February 19, 2013

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Francis S. Collins,  
Director,  
National Institutes of Health

Approved: May 2, 2013

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Kathleen Sebelius,  
Secretary



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